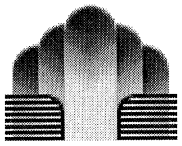
201-14437



Peter Wendol kowski
05/05/2003 12:23 PM

To: Peter Wendolkowski/DC/USEPA/US@EPA
cc:
cc:
Subject: USNPC HPV Final Submission - Cover Letter and Response to EPA's Comments and Suggestions

Ed Kordoski <Kordoski@SOCMA.com> on 04/25/2003 04:30:42 PM

To: oppt.ncic@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA
cc: Dick Waritz <waritz.bio@att.net>, Bill Carroll <bgcarroll@stm.gd-ots.com>, David Shead <david_shead@atk.com>, John Schrader <schrader@usit.net>, Neal Olsen <neal.olsen@am.dynoasa.com>, Jessica Ross <Rossj@SOCMA.com>

Subject: USNPC HPV Final Submission - Cover Letter and Response to EPA's Comments and Suggestions

April 25, 2003

Christine Todd Whitman, Administrator
U. S. Environmental Protection Agency
Post Office Box 1473
Merrifield, VA 22116

Attention: Chemical Right-to-Know Program; HPV Challenge Program; HPV Reference Number:

The Synthetic Organic Chemical Manufacturers Association's (SOCMA) U.S. Nitroglycerin Producers Consortium (USNPC) comprised of Alliant Techsystems Inc., Copperhead Chemical Company Inc., Dyno Nobel Inc., and St. Marks Powder, Inc; is responding to EPA's comments on our robust summaries and test plan for 1,2,3-trinitroglycerin (TNG) commonly called nitroglycerin (CAS # 55-63-O). The EPA's comments and questions were contained in a letter to the USNPC from Mr. Oscar Hernandez, Director, Risk Assessment Division, dated February 20, 2003. The HPV Challenge USNPC robust summaries and test plan were posted for public comment on the ChemRTK HPV Challenge Program Website on October 29, 2002.

The edited and enclosed final HPV document is comprised of a summary matrix of the required SIDS data points indicating the necessary test, test species, protocol used, and the

results; and forty-one individual Robust Summaries. This document differs from the one submitted to the EPA on September 25, 2002, in that it contains the following changes to the robust summaries and test plan:

- The visual "best-fit" line used to obtain the aerobic and anoxic vapor pressure values and boiling point have been replaced by a calculated regression line fit to the data points using LINEST methodology (referenced in the Summaries).

- A published experimental study of the oil/water partition coefficient was recently located in a scientific journal. The original submission based on unreferenced values from data-compilation reference books has been replaced with the published study (Bell, *et al,* 1963 is the reference).

- The EPA expressed the need to identify the primary citation for each robust summary.

  - For the following robust summaries, the citation is now unambiguously identified in either the body or Reference Section. That was the only change that was made to these summaries:

Rat Teratogenicity	Mouse 2-yr. Dietary
Transport Between Env. Compartments	Photodegradation
Biodegradation; Self-Initiating	Water Solubility
Acute Tox to C. *dubia*	Acute Tox to Fathead Minnow
Stability in Water	Acute Tox to Rainbow Trout
I.V. MLD in Rabbits	Acute Tox Alga *S. Caprocornutum*
Skin Sensitization in Humans	Skin Sensitization in Guinea Pigs
Chrom. Abs. in Rat Bone Marrow	Chrom. Abs. In Rat Lymphocytes

Chrom. Abs. In Dog Lymphocytes

Chrom. Abs. Rat Kidney Cells

Chrom. Abs. Dog Kidney Cells

Dom. Lethal Abs. In Rats

In Vitro Mutagenicity to *S. typhimurium*

Gene-Tox in CHO-Kl Cells

Methemoglobinemia Antidote Study

Melting Point

❖ For the following summaries, the citation has been added to the Bibliography and clearly identified in the report body. These are unpublished, privately financed, reports that are not currently publicly available.

8-Day Dietary in Quail

Eye Irritation in Rabbits

Skin Irritation in Rabbits

Dermal LD_{50} in Rats

Acute Oral Tox in Mice

Acute Oral Tox in Rats

Mutations *In Vitro, S. Typhimurium*

Mutations *In Vitro, S. Typhimurium*

(Godek, 1980)

(Barfknecht, 1986)

➢ The EPA expressed the need to compare the reproductive parameters specified by the 1966 U.S. FDA guidelines for the two-generation reproductive toxicity feeding assay in rats to the OECD Guideline 416 study method. This information as been added to the robust summary.

➢ The EPA expressed the need to provide atmospheric photodegradation information. The EPA AOPWIN subprogram software in their EPIWIN suite of environmental predictive software was used for predicting photolysis/photodegradation. The photostability was estimated using that software and found to have a half-life of 116.89 1 hours of sunlight or 9.741 12-hour days which places it in the “slow” atmospheric oxidation potential class.

- It was unclear to the EPA if endpoint values for ecotoxicity studies were based on 10% or 100% active ingredient because a base stock solution of 10% nitroglycerin was used in serial dilutions to provide test concentrations for each endpoint. All endpoint values for ecotoxicity are for 100% active ingredient nitroglycerin and this information as been added to the robust summaries.

In addition to the EPA's comments found in Mr. Hernandez' letter, the EPA recommended that both a *Biodegradation* study using OECD Guideline 301 and a *Genetic Toxicity. Chromosomal Aberration* study using the *in vitro* OECD Guideline 473 be performed. Although the USNPC does not totally agree with EPA's scientific reasoning, we agree to carry out both the *Biodegradation* study and the *Genetic Toxicity.* Chromosomal Aberration* study with nitroglycerin using the appropriate OECD Test Guidelines. These studies will be carried out and reported to the EPA upon completion. These studies will be performed in late 2003 or early 2004.

With these additional comments and clarifications made in response to EPA's questions and remarks, resubmission of the edited final HPV document, and upon completion of the *Biodegradation* and the *Genetic Toxicity: Chromosomal Aberration* studies, the USNPC will have met its obligation in the EPA HPV Challenge Program.

Please contact me at (202) 721-4145 if there are any questions relating to this submission.

Sincerely,

Edward W. Kordoski, MBA, Ph.D.

Executive Director

cc: USNPC Group Members

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Edward W. Kordoski, MBA, Ph.D.
Synthetic Organic Chemical Manufacturers Association
Executive Director, Association Management Center
1850 M Street NW
Suite 700
Washington, DC 20036-5810

Phone: (202) 721-4145
Fax: (202) 296-8120
E-mail: kordoskie@socma.com

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USNPC HPV Final Document Submitted to the EPA on 4-25-2003.doc